

REMARKS

Applicant has carefully considered the Office Action of March 3, 2008 rejecting claims 1-13. The present response is intended to fully address all points of objection raised by the Examiner, and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Regarding the restriction requirement, Applicant wishes to affirm election of Invention I (claims 1-13), and to withdraw Invention II (claims 14-21) from the application, as indicated in the reply filed on January 3, 2008. Claims 14-21 have thus been withdrawn from the application.

Claims 1-13 have been cancelled and re-written, for the sake of clarity and brevity only, in the form of new claims 22-33, in order to overcome the claim objections and rejections under 35 U.S.C. 112. No new matter has been added through the new claims. The Examiner is thus requested to direct his attention to these newly-written claims when considering the arguments contained in this response. Additionally, as required by the Examiner, a substitute specification has been provided addressing informalities throughout, and as noted by the Examiner. No new matter has been added to the specification.

For a reference to anticipate an invention, all of the elements of that invention must be present in the reference. The test for anticipation under section 102 is whether each and every element as set forth in the Claim is found, either expressly or inherently, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the Claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131.

Further, to establish a prima facie case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all of the Claim limitations. *Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970).

Applicant respectfully submits that the cited art, alone or in combination, does not disclose, teach, or suggest all the features of the present claims.

The present subject matter is directed to a novel implant for the treatment of idiopathic scoliosis. The implant has a simple but highly effective design, and allows for the correction of scoliosis in a relatively non-traumatic and minimally invasive manner, in comparison with methods and devices which are currently in use. The implant includes a plate which extends from the upper apex of the scoliotic curve to the lower apex. At either end of the plate is an anchor for anchoring the plate to the spine. Various types of anchors are disclosed in the application.

The plate may comprise a stainless steel material having inherent springiness, as are known in the art (for example, stainless steel #3 or #4). Many embodiments for the exact configuration of the plate are possible, and some examples are illustrated in Figure 2 of the application.

Prior to or during implanting of the implant, the plate is twisted to a predetermined degree that is determined, at least partially, according to the degree and type of deformation of the spine of the patient. The plate is then implanted in the twisted state into the spine in conjunction with the anchors. Following implantation, the plate slowly untwists in a gradual manner. Due to the

connecting of the plate to the spinal column, over a period of time, the de-rotation of the plate causes the spinal column to “untwist” and correct itself in a surprisingly corresponding manner.

It is known that in general in idiopathic scoliosis, the thoracic spine twists towards the right, while the lumbar spine twists towards the left. Through the use of the plate that is twisted on each end in a manner opposite to this, the spinal curvature becomes corrected via the progressive rotational forces applied to it by the implant. Figure 1B of the application shows the plate in the twisted (11) and untwisted (5) configuration. Figure 7B clearly illustrates the general attachment of the plate to the spine, at the upper and lower apexes, while Figures 6A and 6B show attachment of the implant to the spinal vertebrae at each of these apices, with an arrow indicating the direction of correctional forces applied by the implant onto each apex.

Thus, the implant of the present subject matter is formed from three basic parts: the plate, and the two anchors, situated on opposite ends of the plate. It is noted that the plate itself is not directly attached to the spine, and that it is indirectly attached to the spine only at the two apices of the scoliotic curve, through means of the anchors. Thus, the implant is less invasive and traumatic to the body than all implants of the prior art (in cases of more than two scoliotic apices, the plate is preferably anchored at each apex)

As stated in the background of the invention section, currently used treatments for idiopathic scoliosis are all based on *acute surgical correction of the scoliotic curve, and preservation of this correction by using massive metallic implants until fusion of the spine is achieved*. Such procedures involve major surgical trauma, and can pose risks of neurological damage. Many other features make

these surgical treatments unfavorable, such as their high cost, technically challenging procedures, and the massive amount of metal that is retained in the body.

The main prior art which has been raised by the Examiner is U.S. Patent No. 5,672,175 to Martin, which relates to a dynamic implanted spinal orthosis. As stated in claim 1 of Martin, the orthosis is designed “for adjusting the relative positions of spinal vertebrae with respect to a vertical axis comprising anchoring members for securing to the vertebrae and holding means connected to the anchoring members, said holding means including at least one curved holding rod which is flexible and elastic in bending and connected to said anchoring members for anchoring at least two different vertebrae, and coupling means for connecting said holding rod to said anchoring members... for holding the vertebrae in a predetermined corrected position against natural deforming forces...”

The Martin invention is fundamentally different from the implant of the present subject matter. Firstly, *the Martin invention treats each vertebrae individually, attempting to correct the curvature of each vertebrae separately.* This is clearly evident from the language of claim 1 (“...for adjusting the relative positions of spinal vertebrae...”) and from the Figure 1 and its accompanying description. Figure 1 of Martin illustrates five dorsal vertebrae whose positions are to be corrected and maintained using the proposed implant. In between each of these vertebrae is an anchoring component (1) (2) (3), as well as a plurality of coupling means (5a, 5b) (6a, 6b) (7a, 7b), for coupling the anchoring components to a pair of rods (4a) (4b) (see column 8, lines 46-67, and column 9, lines 1-36 of Martin). Thus, for every section of the spine which is to be corrected, the suitable anchoring components, as well as other structural components, must be properly implanted *on each and every*

vertebra! One skilled in the art would be quick to recognize that such an implant is both highly invasive to the body and challenging to properly install on the spinal column. Additionally, the Martin implant is very cumbersome and heavy, containing a lot of metal components, features which make it impractical for real usage.

In sharp contrast to this, the implant of the present subject matter does not treat each and every vertebra individually. Rather, it works by progressive correction of the *whole* scoliotic curve. Attachment to the spine is required *only* at two locations: the upper and lower apexes of the scoliotic curve. Aside from the vertebrae at these two points, there are no other attachment points of the plate to the spine. Remarkably, through the use of a relatively simple and non-cumbersome implant as disclosed in the present subject matter, the entire scoliotic curve is corrected in a progressive and gradual manner, due to the rotational force of the plate exerted on the spine at the anchoring points. The implant is thus highly-practical, much easier to install, and much less traumatic and invasive to the body.

In short, the Martin invention operates in a manner completely different from the implant of the present subject matter. By attempting to correct the curvature of each vertebrae individually, Martin actually *teaches away* from the present subject matter, since by using the implant of the present subject matter, the spinal column is instead treated as a whole entity. In light of the above, it is requested that both the 102 and 103 rejections raised by the Examiner be withdrawn.

It is again noted that the specification has been re-written. The substitute specification contains absolutely no new matter with respect to the original specification. Changes made throughout the specification were done only for the sake of consistency in language, clarity, and

conciseness. For example, the terms “linear enforcer”, “linear plate”, and “enforcer” have all been re-termed simply as “plate”. It is noted that to one skilled in the art, having read the original specification along with the accompanying Figures, it would have been readily apparent that these terms all refer to the same part of the subject matter. Other terms which were previously undefined or unclear have been either eliminated or clearly defined. Thus, the current changes in language have been done for the sake of consistency and clarity only.

In light of the substitute specification provided herewith, withdrawal of all objections to the specification are respectfully requested.

The claims have also been re-written in order to define the scope of the subject matter in a more succinct and clear manner. Here as well, no new matter has been added. The summary of the invention section has been replaced with a new summary of the invention section reflecting the revised claims.

In light of the new claims provided herewith, withdrawal of all objections to the claims, and of all rejections to the claims under 35 U.S.C. 112, are respectfully requested.

In view of the foregoing remarks, further reconsideration and allowance of the application are respectfully requested at an early date.

CONCLUSION

In light of the foregoing, Applicant submits that the application is now in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicant

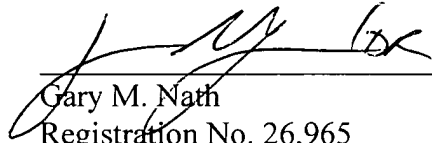
Appl. No. 10/550,189
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respectfully requests that the Examiner contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

Respectfully submitted,
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